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University of Gondar

The Effect of Metoclopramide Prophylaxis for Nausea And Vomiting After Spinal Anaesthesia for Emergency Cesarean Section at the University of Gondar Hospital, Northwest Ethiopia, 2014

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Abbreviations and acronyms

ASA	American Society of Anesthesiologists
BP	Blood Pressure
Bsc	Bachelor science
CD	Cesarean Delivery
CS	cesarean section
CTZ	Chemo Trigger Zone
DC	Data Collector
ETB	Ethiopian Birr
GUECC	Gondar University Ethical Clearance Committee
GUH	Gondar University Hospital
IONV	Intraoperative Nausea and Vomiting
mL	milliliters
cm	Centimeter
MSc	Master of Science
NPO	Non Per Oral
NRS	numeric rating scale
PONV	Postoperative Nausea and Vomiting
RCT	Randomized Control Trail
Sao2	Arterial Oxygen Saturation
SPSS	Statistical Package for Social Sciences
UOG	University of Gondar

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Abstract

Background: - Nausea and vomiting is multifactorial and common problem after spinal anaesthesia for cesarean section which can be unpleasant and disturbing to the patient and making surgery difficult. So that it is sensible to administer prophylaxis drugs with gastrokenitic and antiemetic property for emergency caesarean section. Metoclopramide is believed to be effective to reduce both the incidence and severity of intraoperative and early postoperative nausea and vomiting for cesarean section in some studies. But its effectiveness of reducing the risk of nausea and vomiting after spinal anesthesia for emergency cesarean section was undetermined in our country, Ethiopia. There may be variation in the population demographics and anaesthetic and surgical managements.

Objective: - the aim of this study was to assess the effectiveness of metoclopramide prophylaxis for intraoperative and early postoperatve nausea and vomiting after emergency cesarean section under spinal anaesthesia at GUH.

Methods: - prospective observational study was conducted to assess the effectiveness of metoclopramide. Patients who took 10mg metoclopramide prophylaxis were grouped as group A and without prophylaxis were grouped as group B. pretested observational checklist and interview questionnaire were used to collect the data during CS, and at the 2^{st} , 4^{nd} and 6^{th} hour after cesarean section. Descriptive statistics was calculated for most variables. Student t test or Mann Whitney U tests were used when appropriate. Chi-square and Fisher exact tests were used to compare the proportion of categorical variables between the groups.

Results: - The prophylaxis group with 10mg metoclopramide (n=66) compared with non prophylaxis group (n=66) resulted a significant reduction in the overall incidence of intraoperative and early postoperative nausea and vomiting (25.8% vs. 48.5%, p=0.007). The median score for nausea on a linear numeric rating scale were also reduced in the prophylaxis group [0(0-7) vs. 0 (0-9), p=0.037] at the end of CS and [0(0-6) vs. 0 (0-9), p=0.006] at 2hour and [0(0-6) vs. 0 (0-8), p=0.031] at 4hour. The frequency and number of vomiting episode was also significantly reduced in the prophylaxis group.

Conclusion and recommendation: - Metoclopramide can reduce the incidence and severity of nausea and vomiting when used as prophylaxis before emergency cesarean section under spinal anesthesia.

Keywords: - metoclopramide, Nausea and vomiting, cesarean section, spinal anaesthesia

1. Introduction

1.1 Statement of the Problem

Nausea and vomiting is a very common anaesthetic complication during and after cesarean section under spinal Anaesthesia. From previous studies reported without prophylaxis antiemetic the incidence extremely varies; up to 80% [1, 2]. Nausea and vomiting may result significant distress to the patient and also interfere with the surgical procedure. Consequently it may result aspiration of vomitus, postoperative bleeding and wound dehiscence. The liability of pregnant mothers to nausea and vomiting can be due to hormonal changes to pregnancy attributed by impaired motility of the esophagus, stomach and small bowel as a result of smooth muscle relaxation.[3] The etiology of intraoperative nausea and vomiting is complex; it may be attributed by patient demographic, anesthetic and non-anesthetic causes.[1] Hypotension, surgical stimuli, bleeding during surgery, and uterotonic agents are common offending anaesthetic and surgical causes. As Apfel et.al and similar studies stated previous history of PONV, female gender, motion sickness, none smoking status, longer duration of surgery and use of IV opioids are predictive factors which may affect the occurrence of postoperative nausea and vomiting in the general population. [4, 5]

On the other hand most studies suggested no single intervention is available to eliminate nausea and vomiting completely during cesarean section under spinal anaesthesia; which in fact relied on the anesthetic and surgical techniques used, relative preventive measures taken and multimodal approaches used for superior results than monotherapy in the presence of multiple risks.[2, 6-13] In this regard; strict control offending anaesthetic and surgical factors by adequate preloading/ co-loading with fluids, administration prophylactic vasopressors and 15 degree left uterine displacement[10, 11, 13, 14], optimal use of neuraxial opioids and limited use of systemic opioids, improvement of the surgical techniques, as well as judicious and slow administration of uterotonic agents are believed to be preventive measures to reduce nausea and vomiting[15].

Many systematic reviews and randomized trials have been done to assess of the efficacy of metoclopramide prophylaxis for postoperative nausea and vomiting after elective cesarean section when used as monotherapy or in combination with others.[7, 16-18] Majority of these studies showed administration of 10mg metoclopramide prior to spinal blockage was effective and safe to prevent IONV and early PONV elective caesarean section under regional

anaesthesia.[16, 19] But most of these studies were conducted under control of major intraoperative anesthetic and surgical predisposing factors predictor risks of NV. However in poor setup the availability and applicability of preventive measures for better control of nausea and vomiting in the case of emergency cesarean section questionable.

1.2. Literature Review

Nausea and vomiting after spinal anaesthesia for caesarean section is multifactorial.[20] Hypotension occurring during spinal anesthesia for cesarean section is one of the most important factors.[1, 21] which may trigger the vomiting centre to induce emesis due to hypoxia. And the cause of nausea and vomiting due to hypotension was largely related to spinal anesthesia particularly during higher segmental sympathetic blockade and aortocaval compression [22] and partly when there is fast administration of iv bolus oxytocin as a result of vasodilation.[23] In this regard a bolus lower doses of oxytocin during caesarean section was resulted in less haemodynamic changes than a 5 unit bolus when given before 10u/hour continuous infusion of oxytocin doses.[8, 24] On the other hand intravenous injection of ergometrine found to be less hemodynamic instibilation but can have nausea and vomiting by interaction with dopaminergic and serotinonergic alpha-adrenergic receptors. The incidence of NV was highest among the uterotonic agents with 0.5 mg bolus. However, this drug is usually given intramuscularly which may produce less emesis. [1] Administration of supplemental oxygen during surgery can relieve nausea in such circumstances as previous studies found but recent controlled randomized studies disproved its effectiveness to reduce the incidence of intra- and postoperative nausea and vomiting in women undergoing elective cesarean section under subarachnoid block.[25] But studies stated that distinct association of IONV were found with maternal hypotension and strict control of blood pressure which can considerably decrease intraoperative emetic symptoms.[2, 10, 26, 27]

Systematic review from previous studies suggested strategies to prevent rather than treat hypotension was found to be more likely to decrease the incidence of nausea and vomiting.[10] In this regard lateral uterine displacement, rapid preloading/ fluid co-hydration with 10- 20ml/kg or 1000-1500ml crystalloids and prophylactic vasopressors have been advocated in order to avoid hypotension.[11] However; recent systematic reviews found preloading was unsuccessful to reduce the incidence of relevant hypotension than co loading due to various reasons. This review favored the use of prophylactic vasopressors or combined preload co- load is better than delaying for preloading.

The other important contributing factor for the occurrence of IONV is surgical stimuli or inadequate anesthesia which includes exteriorization of the uterus, intra-abdominal manipulation and peritoneal traction during closure.[34, 35] These maneuvers produce visceral pain that is

mediated by unmyelinated C-fibers.[28] In this regard a comparative study found incidence of post partum nausea was significantly reduced when the uterus was repaired in situ as opposed to after exteriorization(38% vs. 15%) and vomiting was also reduced from 18% to 5%, but was statistically insignificant.[29] On the other hand previous reviews studies stated that the use of intrathecal or i.v opioids reduces the incidence of both IONV and PONV nausea and vomiting by increasing quality of block and reducing visceral pain during surgical manipulation.[9, 30, 31] On the contrary one previous study found some of the commonly used intrathecal or i.v administered opioids predispose to postoperative nausea and vomiting in a dose dependent manner however; reduction the use of opioids was not followed by in the reduction of postoperative nausea and vomiting.[32, 33] In addition intraoperative opioids were not a statistically significant predictor from multivariate logistic regression analyses of a recent large systematic review.[4]

Recent systematic reviews and mata analysis done in USA with eleven studies with 702 patients using spinal anesthesia in nine studies and epidural anesthesia in two studies showed; administration of 10mg Metoclopramide resulted in a significant reduction in the incidence of ION and IOV when given before block placement [relative risk (RR) (95% CI) =0.27 (0.16, 0.45) and 0.14 (0.03, 0.56), respectively. The incidence of early (0–4 h) PON and POV [RR (95% CI) =0.47 (0.26, 0.87) and 0.45 (0.21, 0.93), respectively. And overall (0–24 or 4–24 h) PON (RR 0.69; 95% CI 0.52, 0.92) incidence were also reduced with administration of metoclopramide before block placement.[16]

Comparative randomized double blind placebo controlled study in USA was done to determine the efficacy and safety of 10mg intravenous metoclopramide administered prophylactically before elective cesarean delivery under spinal anesthesia on 42 patients. those patients in the group receiving metoclopramide had a significantly lower incidence of nausea and vomiting both before and after delivery than the control group (saline) 14% and 81% respectively[34]. Similar RCT conducted in India involving 80 elective cesarean sections to compare effects of metoclopramide and other two antiemetic drugs with placebo showed that the incidence of nausea and vomiting intraoperative and up to 4 hours postoperative was 30% in the metoclopramide group and 55% in saline group but the result was stastically insignificant.[35] Similarly a recent randomized clinical trial study aimed to compare the effects of Acupressure and Metoclopramide in 6hours postoperative nausea and vomiting was conducted on 102 patients

in Caesarean Sections in Iran. This study found the incidence of nausea (50% vs. 20%; p=0.03 with 95%CI) and vomiting (32.34%vs 11.76%; p value of 0.01 was significantly lower in Metoclopramide group as compared that in the control group. And the severity of nausea and vomiting within 6 hours after surgery was also significantly reduce with metoclopramide compared with control group.[36]

1.3. Justification of the Study

Previous researches reported women without any prophylactic antiemetic were found higher incidence of nausea and vomiting after caesarean section. The condition is expected to be worse after emergency cesarean section due to presence of potential multiple anesthetic and surgical risks of nausea and vomiting and shortage of time for preoperative optimization. As researches showed in developed countries; in addition to antiemetic prophylaxis; measures to reduce the risks of nausea and vomiting due to hypotension such as rapid rehydration and use of effective prophylactic vasopressors and left lateral uterine displacement and intrathecal administration of short acting opioids and adjuvant with local anesthetics used to reduce visceral stimulation were identified preventive measures to contribute effective control of antiemetic for nausea and vomiting after cesarean section under spinal anaesthesia. However; the availability and use of these measures to minimize the risks of nausea and vomiting are very limited in our country. But, metoclopramide is a generic inexpensive drug with multiple sites of action which is reported to be effective and safe for elective cesarean section. Recently it is advocated to use by some anaesthetists in Gondar university hospital. But as far as our knowledge and search is concerned; there was no previous study that could show the effectiveness of metoclopramide prophylaxis for nausia and vomiting after emergency cesarean section under spinal anaesthesia in our country. This study will enable to know wether or not this 10mg metoclopramide prophylaxis used by anaesthetists before emergency caesarean section is effective to reduce the incidence of intraoperative and early postoperative nausia and vomiting in our setup.

2. Objective

2.1. General Objective

To assess the effectiveness of metoclopramide prophylaxis for nausea and vomiting after emergency cesarean section undern spinal anaesthesia at Gondar university hospital

2.2. Specific objectives

To compare the incidence of nausea and vomiting between metoclopramide prophylaxis and no prophylaxis groups.

To compare severity of nausea between the groups

To compare number of episodes of vomiting between groups

3. Method

3.1. Study Design, Setting and Period

Hospital based prospective observational cohort study was conducted in Gondar university hospital obstetric ward from March 8 to May 8, 2014. On average more than 100 emergency cesarean sections done per month. For majority of cesarean sections spinal anesthesia is the first line anaesthetic technique unless contraindicated by most of anaesthetists in Gondar university hospital. Recently metoclopramide is available with low cost and advocated to use by MSc students and senior anaesthetists as antiemetic prophylaxis for cesarean section. Observations for this study were done in the obstetrics operation room and ward. Groups classified based on their exposure status for metoclopramide (metoclopramide prophylaxis groups and no metoclopramide prophylaxis group) after cesarean section

3.2. Source and study Population

3.2.1. Source population

All women who was delivered by emergency cesarean section under spinal anaesthesia at the University of Gondar hospital

3.2.2. Study population

All women who was delivered by emergency cesarean section under spinal anaesthesia at the University of Gondar hospital

3.3. Inclusion and Exclusion Criteria

3.3.1. Inclusion criteria

All healthy term pregnancy mothers who had emergency caesarean section under spinal anesthesia with available local anestahetics were included in the study.

3.3.2. Exclusion criteria

Any mother having acute or chronic medical illness associated with nausea and vomiting within 24 hours was excluded. Mother who received antiemetic meditation within 24 hours before

surgery indicated. Patients who were given propofol, ketamine, atropine or adrenaline in the intra operative period were excluded. Or mothers who had a concurrent use of an alternative multimodal anti-emetic regimen in the study period were excluded. In addition mothers who had diagnosis of APH and PPH during the study period were excluded.

3.4. Variables

3.4.1. Dependent variable

Nausea and vomiting

3.4.2. Independent variables

Demographic factors: age, weight, height, ASA status, gestational age and parity, previous history of PONV or motion sickness and history of smoking status.

Anesthetic and surgical management: perioperative medications such as opioids, uterotonic agents, antibiotics, and amount of fluid preloaded/coloaded , total intraoperative fluid, type of local anesthetics administered and level of sensory block, duration of surgery/uterus exteriorized, pain, hemodynamic changes(BP, PR, Sao2) after spinal anaesthesia and intraoperative and postoperative analgesics given and supplemental oxygen.

3.5. Operational Definitions

To say the patient has intraoperative and early postoperative nausea and vomiting following cesarean section under spinal anaesthesia, a patient must have at least one episode of nausea, vomiting or both (retching considered as vomiting) in the intraoperative and early (0–6 hours) postoperative period. Severity of nausea was described with 10-mc linear numeric scale (0 without nausea or vomiting,10=very severe nausea).[36] The decrease in systolic blood pressure > 20% of baseline values and/or less than 100 mm Hg immediately after spinal injection will be considered as hypotension.

Amount of fluid co loaded – amount of fluid administered within 20 minutes after spinal placement.

Total amount of fluid administered during operation - total amount of intravenous fluid given starting spinal tap until the end of operation.

Duration of uterus exteriorized - the time when the uterus lifted out of the abdominal cavity during uterine repair.

Sever post anaesthesia shivering refers to patient experiencing more than 3 score of shivering or that manifested with body movement.

Level of spinal block=

3.6. Sampling Technique

3.6.1. Sample Size and Sampling Technique

There is no documented study that shows the incidence of nausea and vomiting (NV) after spinal anaesthesia for cesarean section in study area. However; from recent studies in abroad over all 24 hours incidence of nausea and or vomiting after spinal anaesthesia for cesarean section ranges from 40% to 80% when no prophylactic antiemetic is given.[37] On the other hand based on Apfel simplified risk score and rule of thumb including patients with at least two risk factors assumed to result an average 50% predicted incidence of postoperative nausea and or vomiting.[38] Using proportion difference sample size calculation formula, sample of 66 candidate parturients in each group were calculated to detect 25 % difference(as RCT used) between the groups with 5% alph error at a power of 80%.

3.7. Data Collection procedures

The data were collected using prospective self structured observation checklist and interview-based questionnaire. Candidate parturients were identified and coded by principal investigator based on no prophylaxis given or administration of 10 mg metoclopramide by the responsible anaesthetist within 30 minutes before spinal anaesthesia for caesarean section. The preoperative and intraoperative anaesthetic and surgical managements were continuously observed by one data collector free from the intraoperative anaesthesia management. Oxygen saturation, pulse rate and systolic blood pressure of each woman was monitored and recorded every 5 minutes during the surgery and every one hour post-operatively during the study period. Another data collector interviews each parturients for the presence or absence of nausea and vomiting during operation and every 2hours interval up to 6 hours postoperatively. Severity of nausea was evaluated on a linear numeric scale which ranged from 0 to 10 (no nausea: 0; mild nausea: 1–3; moderate nausea: 4–7; severe nausea: 8–10) at the end of surgery, at 2 hour, at 4hour, and at 6 hours; and number of vomiting episodes in study period. The type of analgesics given to postoperative pain management was identified by the data collector.

3.8. Data Quality Control

To ensure quality of data, pre-test of data collection tools was done on patients by taking 14 respondents (7 who had got metoclopramide prophylaxis and 7 without any metoclopramide prophylaxis) who undergone cesarean section under spinal anaesthesia and were not included in the main study. After the pre-test the data collection tool were modified appropriately. Data was checked for completeness, accuracy and clarity on the day of collection before entered in to database by the Principal Investigator. Data clean up and cross-checking was done before analysis. Training was given to data collectors for one day on how to approach study participants on how to use the data collection tool. Continuous supervision was also done by principal investigator.

3.9. Data Management and analysis

After completion of data collection, the data was checked for errors and coded to numerical values and analysis done using spss version 20. The data were tested for normality using the Shapiro-Wilk normality test and homogeneity of variance as assessed by Levene's Test for Equality of Variances. Baseline demographic characteristics, anaesthetic and surgical management and measures of effectiveness were compared between the study arms using independent *t*-test for Normally distributed data and Mann Whitney U test (MUT) for non normally distributed data and chi square or fisher`s exact test for categorical variables. Normally distributed data presented as Mean ±SD and none normally distributed data presented as median (IQR). Significance level < 0.05 considered statistically significant. Baseline characteristics and risk level was checked for similarity in the groups.

3.10. Ethical considerations

Ethical clearance was obtained from the university ethical clearance committee before the start of the study. The purposes and the importance of the study were explained & verbal informed consent was obtained from each participant by the data collector. Confidentiality was maintained at all levels of the study by avoiding identifiers and using codes to identify patients. Participant's involvement in the study was on voluntary bases, participants who were not willing to participate in the study & those who wish to quit their participation at any stage was informed to do so without any restriction

4. Dissemination of results

The results of the study will be presented to the department of anaesthesia as part of Msc in advanced clinical anaesthesia thesis, communicated through annual students and staff research conference, annual National conference of Ethiopian Anesthetists Association (EAA) and will be sent to the EMJ. The results will also be disseminated to those who can advocate and implement them.

5. Result

5.1. Socio-demographic characteristics of participant:

In this prospective observational study one hundred thirty two emergency cesarean section mothers were enrolled. All cesarean section performed for varieties indications (cephalopelvic disproportion, fetal distress, and failed induction, prolonged rupture of membrane, malpresentation, previous scare and me conium stain). Of these sixty six were mothers who get 10 mg metoclopramide prophylaxis before cesarean section (Group A) and the rest sixty six who were not given the prophylaxis classified as Group B. 13 mothers were having history of surgery and none them had history of smoking. The socio-demographic characteristics (age, weight, height, ASA status, fasting hours and history of PONV / motion sickness) were comparable in both groups, as shown in table 1.

Table 1: Socio-demographic characteristics mothers who underwent emergency cesarean section at GUH in each group, April 2014, North West Ethiopia**.**

Characteristics		Group A (n=66)	Group B (n=66)	p-value
Age(yr)		26.71±4.61	27.33± 5.81	0.498
Weight(kg)		60.03±7.03	58.03±6.63	0.095
Height(cm)		161.77±4.69	161.07±4.77	0.399
ASA (I/II)		62/4	65/1	0.365
Gravidity	-primi-gravida	29(43.9%)	34(51.5%)	0.384
	-Multi-gravida	37(56.1%)	32(48.5%)	
History of PONV/motion sickness		17(25.8%)	21(31.8%)	0.442
Duration of surgery(min)		51.97±10.51	50.59±11.15	0.466
Duration of uterus exteriorized(min)		21.70±5.92	20.32±5.79	0.179
Fasting hours before cesarean section				0.315
	shorter than 6hrs	19(28.8%)	14(21.2%)	
	longer than 6hrs	47(71.2%)	52(78.8)	

Values are given as mean±SD, (%), student t-test and chi-square by 2x2/ (2x>2) table, $\alpha < 0.05$ significant

5.2. Baseline perioperative anaesthetic and surgical characteristics of participants

Baseline perioperative anaesthetic and surgical characteristics of the parturients such as duration of surgery amount of fluid coloaded, total estimated blood loss, number of patients having hypotension after spinal and type of analgesic given for intraoperative postoperative pain management were observed and they were comparable in each group. None of anaesthetists used 15 degree left lateral tilt and no patient was observed to have pulse rate less than 50 during surgery in both groups in the study period. Ten mothers were on induction with oxytocin, 54.5% of patients experienced more than three grade shivering during cesarean section and supplemental oxygen were given for forty two percent of the total study participants but it was comparable between the two groups. The only antibiotic prophylactic given during the study period was ceftriaxone.

Table 2: Baseline perioperative anaesthetic and surgical characteristics of each group of mothers who undergo emergency cesarean section at GUH, April to March 2014, Northwest Ethiopia

Characteristics	Group A (n=66)	Group B (n=66)	P-value
Type of local anesthetics given for block			0.302
0.5% isobaric bupivacaine	29(43.9%)	30(45.53%)	
0.5% heavy bupivacaine	26(39.4%)	19(28.8%)	
2% Lidocaine with adrenaline	11(16.7%)	17(25.8%)	
Level of sensory block at the start of at the time of incision	T6 (T7- T6)	T6 (T8-T6)	
pain complain during surgery	18(27.3%)	25(37.9%)	0.194
type of uterotonic drugs			0.980
oxytocin bolus	20	22	
oxytocin infusion	23	23	
Ergometrine	12	11	
oxytocin + Ergometrine	11	10	
Amount of fluid coloaded	1200(300)	1200(400)	0.085
Total fluid during surgery	1874.24±501.08	1867.27±725.76	0.932
Estimated blood loss during surgery	1050(420)	920(400)	0.078
Fall in SBP >20% from the baseline	36(54.5%)	26(39.4%)	0.081
Analgesic drugs during surgery			0.151
Tramadol(im)	18(27.3%)	26(39.4%)	
Diclofenac (im)	0	1	
postoperative analgesic drugs			0.134
Tramadol (im)	46(69.7%)	35(53%)	
Diclofenac (im)	17(25.8%)	25(37.9%)	
tramadol and diclofenac	3(4.5%)	6(9.1%)	

Values are given as mean±SD, median (IQR), n (%), student t-test/MUT and chi-square by 2x2/ (2x>2) table, $\alpha < 0.05$ significant

5.3. The incidence and severity of intraoperative and early postoperative (0-6hrs) nausea and vomiting

In this observational study, the overall incidence of nausea and vomiting within six hours following cesarean section was 25.8 %(17/66) in metoclopramide and it was 48.5 % (32/66) none metoclopramide group. There were significant differences between groups experiencing nausea and or vomiting. The number of episode of vomiting was significantly lower in Group A compared to group B during and after cesarean section as shown in table 3.

Table 3: *The incidence of intraoperative and postoperative (0-6hrs) nausea and or vomiting in each group of patients who underwent emergency cesarean section at GUH, April 2014, North West Ethiopia*

	parameters	Group A (n=66)	Group B (n=66)	p-value
Intraoperative	nausea	14(21.2%)	26(39.4%)	0.023
	vomiting	7(10.6%)	18(27.3%)	0.015
Early postoperative(0-6hr)	nausea	3(4.5%)	9(13.6%)	0.069
	vomiting	1(1.5%)	7(10.6%)	0.029
overall (intraop - 6hrs) nausea and or vomiting		17(25.8%)	32(48.5%)	0.007

Values refer numbers (%) of patients, chi-square/fisher's exact test, and $\alpha < 0.05$ significant.

In this study the median nausea NRS score experienced by patients during and after CS in each time interval were analyzed. The median value in each interval of time did not clearly show good comparison between groups due to nature of data distribution. The median nausea for group A(metoclopramide group) was significantly lowers than group B at the end of CS, 2hr and 4hr after surgery. Hover ever there was no significant differences severity of nausea at 6hours after CS. (table 4)

Table 4: The comparison of severity of nausea and vomiting between groups

time	group A(n=66)	group B(n=66)	P-value
At the end of surgery	0(0-7)	0(0-9)	0.037
At 2hr	0(0-6)	0(0-9)	0.006
At 4hr	0(0-6)	0(0-8)	0.031
At 6hr	0(0)	0(0-3)	NS
vomiting episodes			0.004,df=3
0	59(87.9%)	41(62.1%)	
1	6(9.1%)	14(21.2%)	
2	2(3%)	7(10.6%)	
3 or more episodes	0	4(6.1%)	

Values are presented as median (interquartile range), number (%), $p<0.05$ significant.

6. Discussion

Spinal anesthesia for cesarean section is preferred anaesthetic technique in most of the setup in the world. Nausea and vomiting after cesarean section are distressing condition that affects up to 80% of cases.[2, 39] The etiology of nausea and vomiting during cesarean section under spinal anaesthesia is complex, and dependent on variety of factors. Hypotension is one offending factor which may cause brain-stem hypoxia and, thus triggers the vomiting center to cause nausea and vomiting. Rapid fluid infusion left uterine displacement, prophylactic vasopressors slow administration of oxytocin advocated to minimize hypotension.[1, 8, 11, 40, 41]In our study; the use of these relative preventive measures were observed less due to in availability and difficulty to apply during emergency cesarean section in our setting. But these factors were comparable between the study groups.

In addition maternal demographics such as age, previous history of motion sickness or postoperative nausea or vomiting [4], pain during uterine exteriorization and peritoneal traction and anaesthetic management considered to affect the occurrence of nausea and vomiting during cesarean section and postoperative period.[37] In this study however, these factors were found balanced between the groups, so that the difference in the incidence of nausea and or vomiting during cesarean section and early postoperative period could be attributed by drug.

In this prospective observational study emergency cesarean section under spinal anaesthesia were included to assess the effects of prophylaxis metoclopramide in the incidence and severity of nausea and vomiting during cesarean section and early postoperative(0-6hours) period. The incidence of nausea and or vomiting were significantly reduce in the metoclopramide group when compared none prophylaxis group (25.8% vs. 48.5%, p=0.007).The frequency and number of vomiting episodes during and after surgery were also significantly reduced. The result was consistent with a number of other previous studies done in India, Iran.[16, 34-36] The effect of metoclopramide and acupressure were compared with placebo on severity of nausea on a linear numeric rating scale in elective cesarean section under spinal anesthesia. This study found that of found that the mean nausea score at 30 minute, 60 minute, 90 minute, 120 minute,2hour, 4hour and 6hour after surgery was significantly reduced compared the placebo.[36] In our study; median numeric nausea score experienced during cesarean section, at 2hr and 4hour postoperative was significantly reduced in the metoclopramide group, but it was comparable at 6 hours post operative time. The reason for this discrepancy may be difference in postoperative pain management, the use of local anesthetics spinal anesthesia and use of weak opoid and NSAIDs for postoperative pain managements that would affect postoperative nausea. The validity to understand the measurement tool might also differ depending on the level of education.

Metoclopramide is a prokinetic drug that acts by increasing the tone of the lower oesophageal sphincter. It also has an antidopaminergic action on the chemoreceptor trigger zone and at higher doses has an anti serotonergic activity. The onset of action after i.v. administration of 10 mg is 1-3 minutes and its half life is approximately 3-4 hours.[1] At lower dose (10mg) was found ineffective in non obstetric surgery under general anesthesia. But previous systematic reviews and majority of randomized controls reported; this dose was found to be effective and safe to reduce the incidence of IONV and PONV in women undergoing cesarean section under regional anesthesia when it was administered prior to block placement as well as after delivery.[16, 20, 34] Some of adverse effects this drug includes sedation, agitation, extra pyramidal and Parkinson symptoms in some cases.[1]

Limitations of the study

The limitation of this study is neither controlled nor randomized observational, we could not control variations in the anaesthetic and surgical techniques and the use of different drugs which

may have confounding. Some variables such as estimated blood loss, amount of fluid preloaded were difficult to measure accurately. The follow up time was short to compare the overall incidence postoperative nausea and vomiting.

Strengths of the study

The strength of this study; it was the first to include emergency cesarean section with different indication for cesarean delivery.

Appropriate analysis methods suitable for nature of variable were used. And inclusion of patients with variety of anesthetic and surgical intervention makes the result generalizable for the university hospitals.

7. Conclusion

Metoclopramide can reduce the incidence and severity of nausea and vomiting when used as prophylaxis before emergency cesarean section under spinal anesthesia.

8. Recommendations

Administration of metoclopramide can reduce the incidence and severity of intraoperative and early postoperative nausea and vomiting when used as prophylaxis before emergency cesarean section under spinal anesthesia. However, this result needs further confirmation of 24 hours effectiveness of metoclopramide with randomization and controlling of confounding factors.

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10. Annexes

Annex I: Information Sheet

Title of the Research Project

Assessment of the effectiveness of metoclopramide prophylaxis on the reduction of nausea and vomiting following cesarean section under spinal anaesthesia in GUH, North West Ethiopia.

Name of Principal Investigator – Nigussie Simeneh (BSc in Anesthesia)

Name of advisors: Adugna Aregawi (MSc)

Habtamu Getnet (MSc)

Name of the Organization: University of Gondar, College of Medicine and Health Sciences, Department of Anesthesia

Name of the Sponsor: University of Gondar Hospital

Introduction

This information sheet is prepared with the aim of assessing effectiveness of prophylaxis metoclopramide in the prevention of intraoperative and early post operative nausea and vomiting prophylaxis following cesarean section under spinal anaesthesia in GUH. The research group includes the principal investigator two data collectors, and two advisors from University of Gondar.

Purpose of the Research Project

The aim of this study is to determine effectiveness of prophylaxis metoclopramide in the prevention of nausea and vomiting following cesarean section under spinal anaesthesia in GUH. Assessing the effectiveness of metoclopramide prophylaxis for nausea and vomiting in patients during cesarean section under spinal anaesthesia is very important to reduce the incidence and severity of nausea and vomiting during cesarean section under spinal anaesthesia by giving appropriate prophylaxis or other preventive measures. The results of this study will be used to design appropriate intervention programs to reduce the occurrence of intraoperative and post operative nausea and vomiting GUH, as well as in other health institutions in Ethiopia.

Procedure

This study will involve candidate parturients coming for operation under spinal anesthesia in the time interval between February -April /2014. Each Study participants will be selected to be one

of the study participants if they are willing to participate in this study and ready to give oral consent.

Benefits, Risk or Discomfort

There is no risk to the participants in participating in this research project because of there is will not be any interventions taken other than observation and some brief interview after CD. However, your participation is definitely important to assess the effectiveness of metoclopramide for nausea and vomiting following cesarean delivery under spinal anesthesia in GUH, to identify factors associated to the intraoperative and postoperative nausea and vomiting and to design appropriate strategy to decrease the incidence of the nausea and vomiting in both groups.

Confidentiality

The information collected from study subjects will be kept confidential and stored in a file, without your name by assigning a code number to it. And hence no report of the study ever identifies the participants.

Right to Refusal or Withdraw

They will have the full right to refuse from participating in this research. They have also the full right to withdraw from this study at any time they wish.

Person to contact

For any questions or concerns you can contact the principal investigator using the following addresses:

Name: Nigussie Simeneh

Telephone: +251 918 441203

E-mail:simenehn@gmail.com

Annex –II: Severity of nausea and vomiting

- **Severity of nausea** will be classified as mild, moderate and severe according to the numerical rating Scale as follows

No nausea worst imagnable nausea

Annex– III: Amharic Version Questionnaire Guide

ጤና ይስጥልኝ፡ስሜ----------ይባላል፡፡ በጎንደር ዩኒቨርሲቲ አንስቴዝያ ትምህርት ክፍል የምርምር ቡድን ውስጥ እየሰራሁ እገኛለሁ፡፡ ወደዚህ የመጣሁበት ምክንያት ከወገብ በታች በቀዶ ህክምና የሚሰጥ ማደንዘዣ ተከትሎ ሊከሰት ስለሚችል

የማቅለሽለሽ እና ትውኪያ መጠን ለሚደረገው ምርምር /ጥናት መረጃ ለመሰብሰብ ነው፡፡ ጥናቱን የሚያካሂዱት በጎንደር ዩኒቨርስቲ አንስቴዝያ ት/ክፍል የሁለተኛ ድግሪ ተማሪ የሆኑት ንጉሴ ስሜነህ ናቸው፡፡

ስለዚህ ከአስር እስከ ሀያ ደቂቃ የሚሆን ጊዜ የሚወስዱ ጥያቄዎች አሉኝ፡፡ የርስዎ ጥያቄዎችን መመለስ ከወገብ በታች ማደንዘዣ ተሰጥተዎት በቀዶ ህክምና ሲወልዱ ሊከሰት ስለሚችል ማቅለሽለሽ እና ትውኪያ ለመቀነስና ለመከላከል ከፍተኛ የሆነ አስተዋፅዎ ይኖረዋል፡፡ ከዚህ የሚገኘው ማንኛውም መረጃ በሚስጥር ይጠበቃል፡፡ ለዚህም ሲባል የርስዎ ስም አይፃፍም፡፡ ለመመለስ ፈቃደኛ ያልሆኑትን ማንኛውም ጥያቄ አለመመለስም ይችላሉ፡፡ በማንኛውም ስዓት የጥያቄና መልሱን ሂደት ማቋረጥ ይችላሉ፡፡ ነገር ግን ቀደም ሲል እንደተገለፀው እርስዎ የሚሰጡት እዉነተኛ ምላሽ ከወገብ በታች በቀዶ ህክምና የሚሰጥ ማደንዘዣን ተከትሎ ሊከሰት ስለሚችል የማቅለሽለሽ እና ትውኪያን ለመቀነስና ለመከላከል ለሚደረገዉ ምርምር / ጥናት በከፍተኛ ሁኔታ ያግዛል፡፡

<u>የቃል ስምምነት</u>

የዚህ ጥናት ዓላማ ተነቦልኝ (አንብቤው) እና አላመው ገብቶኝ በጥናቱ ለመሳተፍ

ሀ. ፈቃደኛ ሆኛለሁ---------- (ቃለ መጠይቁን መቀጠል ይችላሉ)

ለ. ፈቃደኛ አይደለሁም……..(ቃለ መጠይቁን ያቁሙ)

ፈቃደኛ ከሆኑ

የጥያቄው መለያ ቁጥር …….. መጠይቁ የሚካሄድበት ቀን---------- የተጀመረበት ስአት……

የጠያቂው ስም ና ፊርማ---------- ----------

የሱፐርቫይዘር ስም ና ፊርማ---------- ----------

Annex – IV: English Questionnaire

This questionnaire is to be used as a guide to collect information for the data collectors!

Questionnaires to assess effectiveness of prophylaxis metoclopramide intraoperative and 6 hours post operative nausea and vomiting during cesarean section under spinal anaesthesia in GUH, North West Ethiopia.

Hello! My name is ----------I am one of the members of the research team. The purpose of this questionnaire is to gather information on effectiveness prophylaxis metoclopramide in reducing intraoperative and post operative nausea and vomiting during cesarean section under spinal anaesthesia in GUH. I have identified you as a study participant hoping that you would be willing to help me by providing some information. I have some questions which I would like to ask you, if you have the time and are willing. Your participation is definitely important to assess the effectiveness of metoclopramide prophylaxis for nausea and vomiting following cesarean delivery under spinal anesthesia in GUH. All information you provide will be kept confidential. I will not include any identifiers, such as your name or exact address. Only honest answers would

contribute to improvement of health planning. Your role in the success of the research is important and I appreciate your contribution to the research. Would this be okay with you?

I understood about the advantage of the research and the roles I will have in the research. I have agreed to participate in the research.

A. Agree B. disagree

If Respondent agrees to be interviewed, the interview will be started

Questionnaire Code _____

Starting time _____ finishing time _____

Date of data collection_____

Name of data collector_____signature_____

Instruction: For each of the following questions, please circle the number of alternative(s) that fit the response or fill the blank space!

SECTION I: maternal characteristics and predictor risk factors

S.No	**Questions**	**response**
101	maternal age	_____yrs
102	weight	_____kg
103	ASA	A. ASA I C. ASA III B. ASA II D. ASA IV
104	height	_____cm
105	parity	_____
106	Indication for cesarean section?	_____specify.
107	Did you have smoking history?	A. Yes B. No
108	Have you history of surgery and anaesthesia?	A. Yes B. No
109	If yes; have you ever have nausea and or vomiting postoperatively?	A. Yes B. No
110	Have history of nausea or vomiting while travelling by car	A. Yes B. No

SECTION II: baseline preoperative characteristics of patients and interventions

S.No	Questions	response
201	was patient on oxytocin infusion before C/S	A. Yes B. No
202	What was prophylactic antibiotic given?	A. Ampicillin B. Ceftriaxone C. Others_____specify
203	Amount of fluid preloaded within 30 minutes before spinal block	_____ml
204	Fasting hours before cesarean section?	A. less than 6 hours B. greater than 6 hours
205	Base line BP at ward, two measurement before SAB in OR	_____/_____/_____mmHg
206	Base line PR at ward, two measurement before SAB in OR	_____/_____/_____bpm

Section III: intraoperative anesthetic and surgical interventions.

S.No.	**questions**	**response**
	type and baricity of local anesthetics used	A. heavy bupivacaine B. isobaric bupivacaine C. 2 % Lidocaine with adrenaline D. 2 % Lidocaine without adrenaline
301	Volume of local anesthetic?	_____ml
302	Sensory block level before delivery?	_____
304	Does the complain pain during surgery?	A. yes B. no

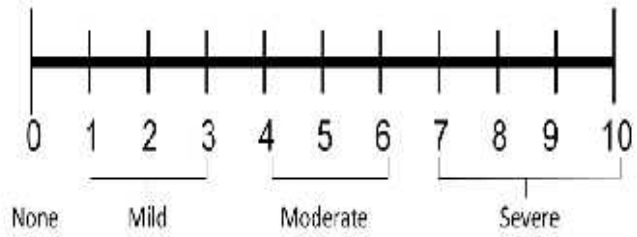
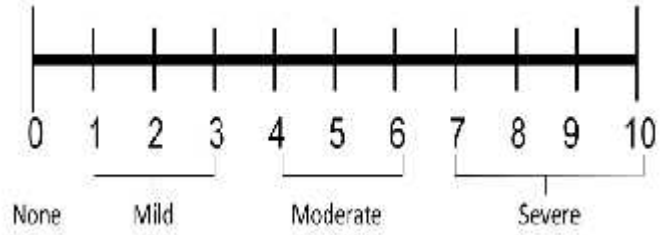
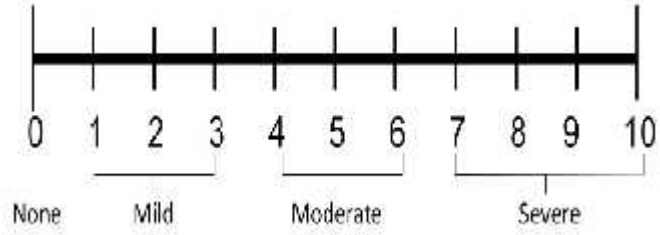
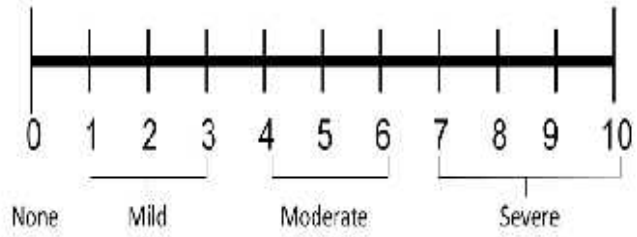
305	If yes, is any intraoperative intravenous supplemental analgesia given?	A. yes B. no
306	If yes, what is given?(total doses intraoperative period)	A. Morphine_____mg B. Fentanyl_____mg C. Tramadol_____mg D. Diclofenac_____mg E. pethidine _____mg
307	Does left lateral tilt or 15 degree wedge uterine displacement used?	A. yes B. no
308	Total amount blood loss including amontic fluid during surgery	_____ml
309	Total intraoperative fluid given during the operation.	_____ml
310	What was given?	A. Normal saline B. Ringer lactate C. DNS D. DW E. Other _____ specify
311	Duration of surgery	_____minutes
312	Duration uterus exteriorized?	_____minutes
313	What type of uterotonic agent was administered after delivery?	A. Oxytocin bolus _____ IU B. Oxytocin infusion _____IU C. Ergometrine_____mg(iv/im,) D. Others_____specify
314	Does patient experience shivering after spinal anesthesia	A. yes B. no
315	Does supplemental oxygen given during the operation?	A. yes B. no

SectionIV: Hemodynamic measurements during surgery and 6hours postoperative

S.No.	questions	response
401	BP (mmHg) at 5, 10, 15, 20, 30,40 minutes after SAB	____/_____/_____/_____/_____
402	PR at 5, 10, 15, 20, 30 minutes after SAB.	____/_____/_____/_____/_____
403	Sao2 at 5, 10, 15, 20, 30 minutes after SAB	_____/_____/_____/_____/____%
404	Was to treatment given for HPT or bradycardia?	A. yes B. no
405	if yes ; what was given	A. adrenaline B. atropine C. dopamine D. others_____specify
406	BP every 1hour interval	_____/ _____/_____ _____/_____/_____mmHg
406	PR every 1hour interval	_____/ ____/_____/____/_____/_____

Section V: The characteristics based on frequency and severity of nausea and vomiting in the intraoperative period, early postoperative period (0-6 hours).

S.No.	questions	response
501	Did you experiences nausea and or vomiting following spinal anesthesia?	A. yes B. no
502	If yes, when it was happened?(follow Q503 to 506)	A. during operation B. early postop (0-6hours)
503	If yes specify your nausea or vomiting i.e. where is your	

	possible feeling to nausea? Based on Visual analogue scale(mark specific interval) **(assess the intraoperative VAS immediately after transfer to ward)** nausea ____ vomiting ____ episode	
504	nausea ____ vomiting ____ episode **at first 2hours**	
505	nausea ____ vomiting ____ episode **at second 2hour**	
506	nausea ____ vomiting ____ episode **at 3rd 2hour**	

Section VI: postoperative managements in the 6hours post-op period (from chart review and interview**).**

S.No.	questions	response
601	When was experience pain after surgery?	A. within 2 hours B. between 2-4 hours interval **C.** between 4-6 hours interval
602	If yes, Was any analgesia given for postoperatively pain management?	A. yes B. no
603	If yes, what was given?(Total dose given over in 6hours postoperatively)	A. Morphine_____mg B. Fentanyl _____mg C. Tramadol_____mg D. Pethidine _____mg E. NSAIDs_____mg F. Others _____ specify
604	When was it given?	A. within 2 hours B. between 2-4 hours interval C**.** between 4-6 hours interval
506	Does any antiemetic administered postoperatively within 6hours	A. yes B. no

Declaration:

I, the undersigned, declare that this thesis is my original work in partial fulfillment of the requirements for the degree of MSc in Advanced Clinical Anaesthesia. I understand that plagiarism will not be tolerated and all directly quoted material has been appropriately referenced

Name: Adugna Aregawi

Signature: _____

Submission to MSc Tutor, Dept. of Anaesthesia, University of Gondar Hospital

Date of Submission: May 23, 2013

This thesis work has been submitted for examination with my/our approval as Advisors and Tutors on the MSc in Advanced Clinical Anaesthesia course (at least one signature required)

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